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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/9,3874	08/11/2003	Kaori Ishimaru	10873-796USWO	5628

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/913,874

Applicant(s)
Ishimaru

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 3, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s).
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5, 6, 7 6) Other:

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DETAILED ACTION

Claims 1-15 are pending. Claims 1-8 are considered on the merits. Claims 9-15 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 9-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group, the requirement having been traversed in Paper No. 9.

Claim 9 may be rejoined upon the finding of an allowable enzyme, if it is limited to a composition comprising the allowable enzyme.

Claim Rejections - 35 USC § 101

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The enzyme exists in nature and is not claimed in isolated or purified form.

Claim Rejections - 35 USC § 112

DEPOSIT

Claims 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism.

As the deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

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Assurance may be provided in the form of an affidavit, declaration or averment under oath or by a statement of the attorney of record over her or his signature and registration number.

The specification must also state the date of deposit, the number granted by the depository and the name and address of the depository. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/48043 [N].

The claims are directed to a protease which releases an amino acid having a glycosylated α -amino group from a glycosylated protein or peptide and a method for quantitating a glycosylated protein comprising treating the sample with a protease that hydrolyzes the amino acid having a glycosylated α -amino group and treating the hydrolyzed sample with fructosyl amino acid oxidase to catalyze a redox reaction and quantitating the reaction.

The references are relied upon as explained below.

WO 98/48043 in Table 1 and Table 2 discloses various proteases which have been used to hydrolyze glycosylated proteins. While the reference does not reveal whether or not the proteases are capable of releasing a single glycosylated amino acid, the proteases listed (1) have been used to determine the amount of glycosylated protein in the same test method as the instant one; and (2) the proteases listed are fairly non-specific, so that given enough time, a single glycosylated amino acid, such as a glycosylated valine if present, could reasonably be expected to be released from a glycosylated protein.

Insofar as these processes rely on the use of an enzyme which instead of being characterized by technical features suitable for the identification of an enzyme, is imprecisely defined by means of functional features which merely recite

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the desired result to be achieved, the subject matter is considered to be anticipated by the disclosures of the prior art until objective evidence is presented to disprove this reasonable assumption. Further, as the trade names for the enzymes are used in Tables 1 and 2 or the references, it is unclear if any of these are derived from the genus *Pseudomonas* or *Corynebacterium*. It is assumed that at least some of them are until a statement to the contrary is provided.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 97/20039 [O].

WO 97/20039 discloses a method of quantitating glycated hemoglobin using a protease, aminopeptidase, example 5. Since the glycated substrate is the same as in the instant application and the detection system comprising FAOD is the same as in the instant case, the protease, aminopeptidase, is considered to have the same functional characteristics as the enzyme in claim 1.

Claims 1, 4-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shin et al. [IDS].

The claims are directed to a protease obtained from *Pseudomonas (alcaligenes)* having the ability to release an amino acid having a glycated α -amino group from a glycated protein.

Shin et al. discloses a protease derived from *P. alcaligenes* which has the ability to hydrolyze various proteins.

Claims 1, 4 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 50-19628 [IDS].

JP 50-19628 discloses a protease derived from *Pseudomonas* which hydrolyzes hemoglobin.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 63-279782 [IDS].

JP 63-279782 discloses protease obtained from three species of *Corynebacterium*.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' enzyme differs and, if so, to what

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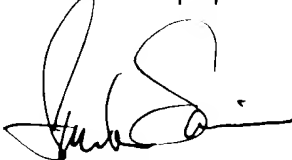
extent from the enzymes discussed in the references. Accordingly, it has been established that the prior art enzymes, which are obtained from the same genus and species and share the property of being able to hydrolyze proteins demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known enzyme is not disclosed in a reference does not make the known enzyme patentable. The known enzyme possesses inherent characteristics which might not be displayed in the tests used the reference. However, the enzyme disclosed may be the same enzyme as claimed. Clear evidence that the enzymes of the cited prior art do not possess a critical characteristic that is possessed by the claimed enzyme, would advance prosecution and might permit allowance of some of the claims.

Claim 3 appears to be free of the art.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. **Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198.** The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
February 28, 2003